**Sample Letter of Medical Necessity**

*Note to physician: this template may be used to help create your institution’s independent letter of medical necessity to be sent to a patient’s health plan to determine/request coverage, if required. All pink, bracketed content needs to be filled out based on the details of each specific patient. Be sure to review and understand specific health plan requirements for your patient. It is also important to understand each plan's submission process (online vs fax).*

[Date]

[Health plan name] [Patient’s Name]

ATTN: [Department] [Patient’s plan-specific member ID]

[Medical/Pharmacy Director Name (if available)] [Date of birth]

[Health plan address] [Case number]

[City, State, ZIP Code] [Dates of service]

Re: Letter of Medical Necessity for PLUVICTO® (lutetium Lu 177 vipivotide tetraxetan)

Dear [Medical/Pharmacy Director Name],

My name is [HCP name], and I am a [medical specialty]. I am writing this letter of medical necessity on behalf of [Patient’s Name] to request coverage for PLUVICTO for the treatment of [product indication] [insert ICD-10 code(s)]. This letter provides the clinical rationale and relevant information about the patient’s medical history and treatment.

I have been treating [Patient’s Name], [a/an] [age]-year-old patient since [Date]. My rationale for prescribing PLUVICTO is: [Include relevant medical information and/or documentation and explain why PLUVICTO is the most appropriate treatment option. Examples may include:

* Provide clinical support for your recommendation as to why PLUVICTO is the most appropriate treatment option (this can be clinical trial data from the PLUVICTO prescribing information)
* Share that lutetium lu 177 vipivotide tetraxetan (PLUVICTO®) is an NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) recommended option for patients with metastatic castration-resistant prostate cancer (mCRPC)\*
  + NCCN Category 1† recommended, useful in some circumstances, for prostate-specific membrane antigen (PSMA)-positive (PSMA+) mCRPC patients with progression on androgen receptor pathway inhibition (ARPI) and prior docetaxel chemotherapy
  + NCCN Category 2A‡ recommended, useful in certain circumstances, for mCRPC patients with:
    - At least 1 PSMA+ lesion and/or metastatic disease that is predominantly PSMA+
    - No dominant PSMA-negative metastatic lesions
    - Progression on prior androgen receptor-directed therapy and **no prior taxane-based chemotherapy**

\*NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

†A Category 1 rating is based upon high-level evidence; there is uniform NCCN consensus that the intervention is appropriate.

‡A Category 2A rating is based upon lower-level evidence; there is uniform NCCN consensus (≥85% support of the Panel) that the intervention is appropriate.

* Detail any of the patient’s comorbidities that could serve as contraindications to certain other treatments
* Explain why the health plan’s preferred therapies are not appropriate for your patient
* If your patient is already taking PLUVICTO, describe their response to PLUVICTO and explain why it is not in the best interest of your patient to stop or switch therapies
* Provide your professional opinion of the patient’s likely prognosis or disease progression without treatment with PLUVICTO

In my medical judgment, this patient is an appropriate candidate for treatment with PLUVICTO. I have included the full prescribing information for PLUVICTO, as well as supporting clinical data.

If you have any further questions about this matter, please feel free to contact me at [physician phone number] or via email at [physician email]. Thank you for your time and consideration.

Sincerely,

[Physician’s signature] [Physician name] [Physician NPI] [Name of practice] [Phone number]

Enclosures: [List and attach additional documents, which may include prescribing information, clinical notes/medical records, testing or imaging results, clinical studies and efficacy data, PA number, and/or clinical practice guidelines.]

*This letter is provided as an example and is meant for educational purposes only. Novartis cannot guarantee insurance coverage or reimbursement. Coverage and reimbursement may vary significantly by payer, plan, patient, and setting of care. It is the sole responsibility of the health care provider to include the proper information and ensure the accuracy of all statements used in seeking coverage and reimbursement for an individual patient.*

**INDICATION & IMPORTANT SAFETY INFORMATION**

**INDICATION**

PLUVICTO®(lutetium Lu 177 vipivotide tetraxetan) is indicated for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibition (ARPI) therapy, and

* are considered appropriate to delay taxane-based chemotherapy, or
* have received prior taxane-based chemotherapy

**IMPORTANT SAFETY INFORMATION**

**Risk From Radiation Exposure**

PLUVICTO contributes to a patient’s long-term cumulative radiation exposure, which is associated with an increased risk

for cancer.

Minimize radiation exposure to patients, medical personnel, and others during and after treatment with PLUVICTO consistent with institutional practices, patient treatment procedures, Nuclear Regulatory Commission patient-release guidance, and instructions to the patient for follow-up radiation protection.

Ensure patients increase oral fluid intake and advise them to void as often as possible to reduce bladder radiation.

To minimize radiation exposure to others, advise patients to limit close contact (less than 3 feet) with household contacts for 2 days or with children and pregnant women for 7 days, to refrain from sexual activity for 7 days, and to sleep in a separate bedroom from household contacts for 3 days, from children for 7 days, or from pregnant women for 15 days.

**Myelosuppression**

PLUVICTO can cause severe and life-threatening myelosuppression. In the PSMAfore study, grade 3 or 4 decreased hemoglobin (7%), decreased leukocytes (4.4%), decreased neutrophils (3.5%), and decreased platelets (2.7%) occurred in patients treated with PLUVICTO. One death occurred due to bone marrow failure during long-term follow-up in a patient who received PLUVICTO. In the VISION study, 4 myelosuppression-related deaths occurred.

Perform complete blood counts before and during treatment with PLUVICTO. Withhold, reduce dose, or permanently discontinue PLUVICTO based on severity of myelosuppression.

**Renal Toxicity**

PLUVICTO can cause severe renal toxicity. In the PSMAfore study, grade 3 or 4 acute kidney injury (1.3%) occurred in patients treated with PLUVICTO.

Advise patients to remain well hydrated and to urinate frequently before and after administration of PLUVICTO. Perform kidney function laboratory tests, including serum creatinine and calculated creatinine clearance (CrCl), before and during treatment. Withhold, reduce dose, or permanently discontinue PLUVICTO based on severity of renal toxicity.

**Embryo-Fetal Toxicity**

The safety and efficacy of PLUVICTO have not been established in females. Based on its mechanism of action, PLUVICTO can cause fetal harm. No animal studies using lutetium Lu 177 vipivotide tetraxetan have been conducted to evaluate its effect on female reproduction and embryo-fetal development; however, radioactive emissions, including those from PLUVICTO, can cause fetal harm. Advise males with female partners of reproductive potential to use effective contraception during treatment with PLUVICTO and for 14 weeks after the last dose.

**Infertility**

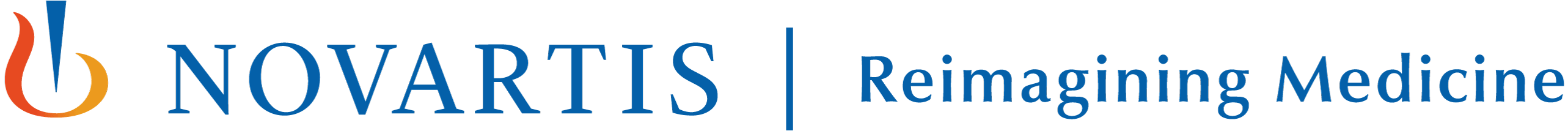
The recommended cumulative dose of 44.4 GBq of PLUVICTO results in a radiation-absorbed dose to the testes within the range where PLUVICTO may cause temporary or permanent infertility.

**Adverse Reactions and Laboratory Abnormalities**

In the pooled safety population for the PSMAfore and VISION studies (N=756), the most common (≥20%) adverse reactions, including laboratory abnormalities, were decreased lymphocytes (83%), decreased hemoglobin (65%), fatigue (49%), dry mouth (46%), decreased platelets (40%), decreased estimated glomerular filtration rate (37%), nausea (35%), decreased neutrophils (31%), decreased calcium (29%), decreased sodium (27%), increased aspartate aminotransferase (26%), increased alkaline phosphatase (24%), arthralgia (22%), decreased appetite (21%), increased potassium (21%), constipation (21%), and back

pain (21%).

**Please see full**[**Prescribing Information**](https://www.novartis.com/us-en/sites/novartis_us/files/pluvicto.pdf)**.**



**Novartis Pharmaceuticals Corporation**

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